REMARKS

All the claims submitted for examination in this application have been rejected on formal and substantive grounds. Applicants have amended their claims and respectfully submit that all the claims currently in this application are patentable over the rejection of record.

Turning to the first formal ground of rejection, Claims 9-12 stand rejected, under 35 U.S.C. §112, first paragraph, as not being enabled. The Official Action avers that although the specification is enabling for reducing the pH throughout the colon and increasing the amount of butyrate in the colon, it does not provide enablement for treating, managing or preventing lactose intolerance, food allergy, inflammatory bowel disease or celiac disease by application of polydextrose.

To overcome this ground of rejection each of Claims 9-12 have been amended to add the further limitation that the aforementioned conditions are lactic acid induced. When this added limitation is introduced, it is apparent that the specification fully supports the scope of amended Claims 9-12 wherein polydextrose is administered in an amount effective to reduce the aforementioned conditions induced by lactic acid.

Attention is directed to the specification at Page 9, lines 14-18. Therein it is stated that imbalanced fermentation may cause disease or disorders such as acidosis, inflammation, allergy, celiac disease, osteoporosis, etc. due to the uncontrolled accumulation of lactic acid. In addition, the specification provides, in Examples 2-4, support for the propositions that polydextrose increases butyric acid and decreases branched volatile fatty acids (VFAs), which is a biomarker for undesirable fermentation. Moreover, the working examples demonstrate that polydextrose causes no accumulation of lactic acid.

The aforementioned disclosures in the specification establishes enablement of the method set forth in Claims 9-12. That is, the specification provides support for the fact that diseases enumerated in Claims 9-12 are caused by imbalanced fermentation and that the working examples demonstrate that polydextrose increases production of butyric acid, decreases branched VFAs and causes no accumulation of lactic acid. This establishes that polydextrose, which prevents accumulation of lactic acid throughout the colon, is effective against the lactic acid induced disorders of Claims 9-12.

The aforementioned remarks are predicated on well-established scientific fact. The mucosal of the colon is covered with a mucous layer protecting the underlying epithelium. Microbial fermentation in the colon produces short chain fatty acids (SCFAs), which are known to stimulate mucous release from colon epithelia. SCFAs are also known to restore a mucosal barrier after irritation. However, during unbalanced colonic fermentation, SCFAs are reduced and lactic acid concentration is increased, causing reduced mucous release and mucosal blood flow. Decrease in the protecting mucous gel layer can lead to diarrhea, mucosal damages and increased diffusion of antigenic compounds including microbes, toxins and proteins to blood circulation. This increased intestinal permeability may cause abnormal antigen exposure known to be associated with such disorders as inflammatory and celiac diseases, allergies and the like. This information, known to those skilled in the art, provides adequate enablement for the methods of Claims 9-12.

It is furthermore emphasized that the allegation that experimentation is required to practice the invention commensurate to the scope of the claims, is not the case. That Examples 2-4 of the specification establish that polydextrose increases butyric acid production, decreases branched VFAs and causes no accumulation of lactic acid, respectively, which affects, prevents

or alleviates the diseases or disorders of Claims 9-12 substantiate applicants' allegation that no undue experimentation is required.

That the specification, at Page 19, lines 9-14, even recites the amount of polydextrose required to be administered to human beings further establishes that the method of Claims 9-12 is clearly enabled by the specification of the present application.

The second formal ground of rejection is directed to Claims 1, 5-14, 16-28 and 30-34. Claims 1, 5-14, 16-28 and 30-34 stand rejected, under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The alleged indefiniteness of Claim 1 is predicated upon the supposition that those skilled in the art do not appreciate what conditions or diseases result from lactic acid accumulation. Thus, the Official Action concludes, it is impossible to determine the metes and bounds of this claim.

This basis for rejection overlooks the fact that diseases associated with imbalanced colon fermentation, caused by lactic acid accumulation, are set forth in the specification at Page 9, lines 14-18. As such, guidance is clearly provided to those skilled in the art as to the metes and bounds of Claim 1.

As far as the second specified ground in support of this indefinite rejection is concerned, that ground is directed to Claim 23. Therein, the term "sour" is questioned insofar it refers to a sour food or feed product.

Claim 23 has been cancelled. However, "sour milk" is one of the food products within the scope of the Markush group of Claim 1 to which polydextrose is added. Those skilled in the food arts are aware that sour milk merely refers to milk of lower pH. That sour milk is

acidic, often caused by bacterial culture, and encompasses such well-known products as buttermilk is well known to those skilled in the food arts. Certainly, those skilled in the art are aware of the product denoted by this term.

Three substantive grounds of rejection are imposed in the outstanding Official Action. The first of these is directed to Claims 1, 5-13, 19, 27 and 28. Claims 1, 5-13, 19, 27 and 28 stand rejected, under 35 U.S.C. §102(b), as being anticipated by Jie et al., *Am. J. Clin. Nutr. 72*:1503-1509 (2000).

It is unnecessary to consider the basis upon which this ground of rejection is imposed. Suffice it to say, this ground of rejection does not include Claim 25 therein. Claim 25 limits the method of Claim 1 to a Markush group of foods to which the method of the present application has been limited. Insofar as Jie et al. makes no disclosure of any of these foods, it is apparent that the absence of Claim 25 from this anticipatory ground of rejection is appropriate.

Since dependent Claim 25 has been redrafted in independent form, as amended Claim 1, it is apparent that the claims subject to this ground of rejection, which include the limitation of original dependent Claim 25, are novel over the applied Jie et al. reference.

The second substantive ground of rejection is directed to Claims 1, 5-14, 16-19, 21, 22, 26-28 and 30-34. Claims 1, 5-14, 16-19, 21, 22, 26-28 and 30-34 stand rejected, under 35 U.S.C. §102(b), as being anticipated by International Publication No. WO 00/40101 to Olinger et al.

As in the first ground of rejection, it is unnecessary to elaborate on the alleged grounds for anticipation of these claims by Olinger et al. Suffice it to say, Claim 25 is not amongst the claims subject to this ground of rejection. The incorporation of the limitation of Claim 25 into all of the claims subject to this ground of rejection, by incorporation of dependent

Claim 25 into amended Claim 1, establishes novelty of these claims over the applied Olinger et al. reference.

The third and final substantive ground of rejection is directed to Claims 20-25. Claims 20-25 stand rejected, under 35 U.S.C. §103(a), as being unpatentable over Jie et al.

The Official Action argues that it would have been obvious to one skilled in the art to administer polydextrose to subjects having conditions associated with digestive and bowel health insofar as Jie et al. teaches that consumption of polydextrose improves bowel function, softens feces, improves ease of defecation and promotes proliferation of favorable intestinal microflora and decreased pH of the bowel. The Official Action further states that one skilled in the art would easily conceive of administering that polydextrose in the form of a food composition.

Applicants respectfully submit that the conclusion that it would have been obvious to one skilled in the art to include polydextrose in a food product is not suggested by Jie et al. Jie et al. teaches the introduction of polydextrose in a non-food product. That is, Jie et al. teaches the introduction of polydextrose taken in a glass of warm water (Page 1504, left column, lines 6-7 below Table 1).

The present amendment of Claim 1, however, is even further removed from the teaching of Jie et al. Not only does Jie et al. not teach the introduction of polydextrose in a food product but, in addition, the amended claims of the present application are limited to specific food products, which are all dairy products. That is, yogurt, baby's milk formula, sour milk, curdled milk, dry milk and crout are all dairy products to which all the claims of the present application are limited.

The irrelevancy of Jie et al. is emphasized by the type of products ingested by the subjects of that article. Those products are set forth at Page 1504, left column of Jie et al. in the section denoted as "Feeding." Therein, it is stated that the meals were prepared as typical Chinese food. Those skilled in the food arts appreciate that Chinese cuisine is devoid of dairy and milk products. As such, even if an argument was raised that the replacement of water with foods as the vehicle for the administration of polydextrose was obvious to one skilled in the art, a proposition which applicants strenuously deny, still the foods to which the polydextrose would be added would be far removed from the limited class of foods within the scope of the claims of the present application.

Yet another basis for patentability over this ground of rejection, introduced in the present amendment, is the well-known fact that milk-based products yield lactic acid upon fermentation. That the limited class of food products within scope of the amended claims of the present application are rich in lactose and yield lactic acid upon fermentation make it unobvious to one skilled in the art to utilize such foods to prevent accumulation of lactic acid in the colon and thus utilize such a composition, in combination with polydextrose, to prevent such accumulation.

It is furthermore noted that, as stated in the Official Action, Jie et al. teaches that the consumption of polydextrose increases the amount of *Lactobacillus* and *Bifidobacterium*. Furthermore, as stated in the Official Action, Hove et al., *Am. J. Clin. Nutr., 59*:74-79 (1994) demonstrates that the presence of lactic acid bacteria in the colon does not change the pattern of colonic fermentation or the degree of intestinal lactose malabsorption. However, Hove et al. shows, in the sentence bridging Pages 75 and 76 and in Table 2, that lactose considerably increases production of lactate and that *Bifidobacterium* does not prevent the production of

lactate. Table 2 shows that the addition of 10 g/L of lactose raised the amount of lactate, e.g. lactic acid, quite considerably, despite the *Bifidobacterium* presence.

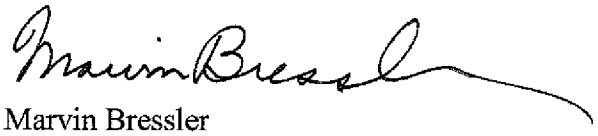
Based on these teachings, one skilled in the art would know that polydextrose increases the amount of *Lactobacillus* and *Bifidobacterium* in the intestine. However, this understanding would not have resulted in the expectation that this would not influence accumulation of lactic acids, since Hove et al. teaches that these microbes do not prevent the accumulation of lactic acid.

The present application discloses that polydextrose not only provides a beneficial dietary fiber-like effect, with no laxative problems, as also concluded by Jie et al., but that polydextrose, as it proceeds through the colon, provides energy to the microflora in a controlled and sustained matter and thus enables the microflora to continuously consume lactic acid. Clearly, this teaching which is embodied by the method of the amended claims of the present application, is not made obvious by the applied references.

The above-extended remarks establish the patentable nature of all the claims currently in this application over the substantive grounds of rejections imposed in the Official Action. Reconsideration and removal of these grounds is therefore deemed appropriate. Such action is respectfully urged.

The above amendment and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1, 5-14, 16-20, 24, 26-28, 30 and 32-34, is respectfully solicited.

Respectfully submitted,



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